

Developing

QC

Materials For

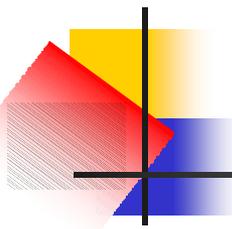
GENETIC TESTING

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Department of Health and Human Services
Centers for Disease Control and Prevention

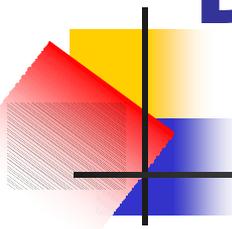




Expert Panel Recommendations for Molecular Genetic Tests

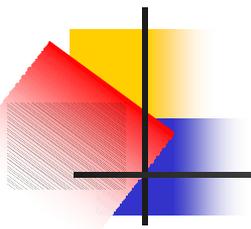
Conduct research to develop positive controls for Quality Assurance (QC/PT) for genetic tests.

- Use existing immortalized cell lines
- Investigate alternative test materials



Developing a Sustainable Process

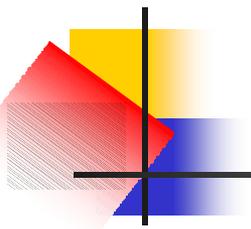
- How can QC/PT Materials for genetic tests be obtained?
- How can QC/PT materials be validated?
- How can QC/PT Materials be collected and stored?
- How can QC/PT materials be distributed at a reasonable cost ?



Conference Agenda

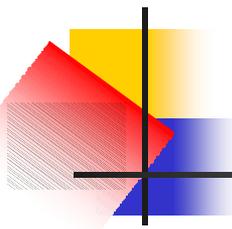
September 15-16, 2003

- Current QC Materials for Genetic Tests
- Research to Develop Materials for QC/PT
- Unmet and future needs?
- Applicability of research to address needs?
- Mixer to discuss research
- Practical issues – validation and cost
- Bridging the gaps and sustaining a process



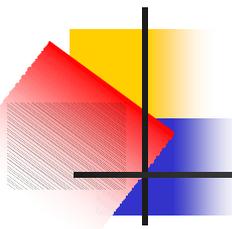
Applicability: Questions to Answer?

- Which unmet needs are easy to address?
- Which unmet needs are difficult to address?
- What are the strengths and weakness of the various methods to address needs?
- Would licensing pose a major or minor impediment to development and use of QC materials?



Practical Matters: Questions to Answer?

- Where are the areas of greatest need?
- How important is validation of QC materials?
- Can PT be used to validate QC materials?
- How can QC materials for rare diseases be obtained?
- What is an acceptable charge for QC materials?



Gaps and Sustained Process: Questions to Answer?

- Who should play a role in development of QC materials?
- Who should play a role in validation of QC materials?
- Who should play a role in collection and storage of QC materials?
- Who should play a role in distribution of QC materials?
- Who should pay the bill for QC materials?



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